CLINICAL ETHICS

Can patients be sure they are fully informed when representatives of surgical equipment manufacturers attend their operations?

M Sillender

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Correspondence to: Mark Sillender, 4 Wexham Lodge, Wexham Road, Wexham, Berkshire, S12 4HF, UK; marksillender2@hotmail.com

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Objective: To determine the practice in UK hospitals regarding the level of patient involvement and consent when representatives of commercial surgical device manufacturers attend and advise during operations.
Methods: An anonymous postal questionnaire was sent to the senior nurse in charge in all 236 UK gynaecology theatres in 2004. 79/236 (33%) replies were received.
Results: Operating departments were visited every 2 weeks on average by a representative of the surgical device manufacturer. Actual operations were attended every 10 weeks, although there was much variation. 33/79 (42%) units consistently obtained patient consent for visits, usually orally, whereas 40/79 (51%) units did not. 65/79 (82%) units had no guidelines for surgical device representative visits. 91% of nurses in charge believed that there should be guidelines to protect both patients and staff. 6/79 (8%) units were preparing local guidelines at the time of the survey.
Conclusions: Currently, patient safety, confidentiality and autonomy are being protected by a minority of NHS operating theatres when surgical device representatives attend surgery. National guidelines would hopefully ensure that fully informed patient consent is obtained and that representatives are fully trained and supervised.

Representatives of surgical device manufacturers often visit operating theatres. As complex and innovative surgical technology becomes more prevalent, there is an increasing need for technical advice from representatives during surgery.

There are, however, concerns about commercial visitors in theatre. Do patients give informed consent for the representatives to be present? Just as importantly, are the representatives appropriately trained in patient safety, theatre etiquette, legal issues and infection control?

This paper describes the practices of UK operating theatres providing gynaecological surgery in 2004. Are patients' rights and safety protected when commercial representatives exhibit their products?

METHODS

An anonymous questionnaire was sent to the senior nurse in charge of the operating theatre of all 236 UK NHS gynaecology units listed on the Dr Foster website.[1]

A self-addressed envelope was enclosed for the reply. To preserve anonymity, responses were not tracked against the list of units. Follow-up questionnaires were therefore not sent.

The questionnaire requested information on the following:

- The frequency of visits by representatives to the operating department and how often they actually watched surgery
- Whether patients routinely gave consent for the representative to be present and, if so, whether the consent was written or oral
- Awareness of guidelines covering visits by representatives and patient consent (copies were requested if guidelines were available)
- Their opinion on whether guidelines should be provided and why, and what the guideline should contain.

RESULTS

Of the 236 questionnaires that were administered, 79 were returned, a response rate of 33%.

Visit frequency

We observed a large variation in the number of visits by representatives, which was probably due to the different sizes and types of hospital, and because some gynaecology theatres were in a separate location from the general theatre block. The usual frequency of visits was fortnightly, but of the 79 units, 11 were visited several times a week. Five units saw a representative only once a year or less and two units saw representatives only on request.

It was much less frequent for a representative to actually go into a theatre during an operation. The average was about once every 10 weeks, although, again, there was marked variation, ranging from more than once a week to never.

Consent

In all, 40/79 (51%) units reported that patient consent for the representative to be present was not usually sought and 33/79 (42%) units said that consent was consistently obtained. A further 4 (5%) units sometimes received consent. All units, with the exception of one, relied on oral rather than written consent.

Guidelines

Of the 79 units, 10 (13%) did have guidelines in place, but only three examples were forwarded. One of these was a technical guideline relating to the use of new equipment and it did not refer to patients. The other two guidelines were comprehensive and patient centred. At least one unit was ''not allowed'' to forward its policy.

The nurses in charge in 65/79 (82%) units said they did not have any guidelines at all. Of the senior nurses responding to the survey, 59/79 (91%) thought that written guidelines

should be available, 4 thought there should ''possibly'' be guidelines and 6 (8%) units were preparing local guidelines at the time of the survey.

Free text responses

The most common themes were the need for written patient consent, protection of patients when new equipment was used and preservation of patient confidentiality. Several respondents wanted a more structured approach to visits, with compulsory prebooking, photographic identification and visitors' diaries. They also wanted to see evidence of training in confidentiality, theatre safety and etiquette.

DISCUSSION

Public opinion is increasingly critical of clinical practice.[2] Incidents like the UK paediatric organ affair have shown that we should regularly examine practice to ensure that it remains acceptable.[3]

This survey suggests that much can be done to improve standards when non-clinicians attend surgical operations, especially with gaining consent. A response rate of 33% in this study may lead to criticism that a biased response was obtained, but it was necessary not to keep a log of respondents to maintain anonymity. Non-responding units probably do not have practices that are superior to those replying. The number of units that did reply and had not dealt with these standards is worrying.

Informed patient consent is particularly important in modern medicine. Patients in the UK have strong views about their rights to give or withhold consent in healthcare. A recent study[4] showed that patients want the opportunity to give or withhold consent for the gathering of information in which anonymity was preserved for research purposes from their notes. They were very suspicious of any commercial involvement. They considered fully informed consent to be an important measure of respect for their individuality. It is logical, therefore, to suppose that patients are likely to regard the presence of a commercial representative during their surgery as important and unacceptable without consent.

The Department of Health published an updated guide to consent in March 2001,[5] which referenced the incorporation of the European Convention on Human Rights[6] into English law. Article 8 of the Convention states that ''everyone has the right to respect for his or her private & family life.'' Further guidance[7] states that ''anyone who is invited into hospitals or areas of clinical care in an advisory capacity is bound by the same legal and ethical obligations as those employed within the NHS.''

The General Medical Council's detailed guidance on consent[8] emphasises patient autonomy and advises withholding information only if serious harm can result. Here, ''serious harm does not mean the patient would become upset, or decide to refuse treatment.''

Therefore, according to legislation and guidance by the General Medical Council and NHS, hospitals and their staff have a legal, contractual, professional and ethical obligation to ensure that the presence of representatives during surgery is discussed fully with patients.

Some clinicians may discuss the presence of representatives informally with patients without documenting it in the notes or discussing it with theatre staff. It is difficult to ascertain to what extent this occurs and whether it would reduce the large number of units where consent is not said to be obtained. A lack of documentation still leaves the units and clinicians open to criticism. We need to be systematic and be able to clearly show adherence to standards. It is important to work together with patients and be open about all aspects of their care.[9] Time is needed for the patient to question, reflect and decide whether to give consent. A quick oral discussion in the anaesthesia room just before surgery is not ideal.

Table 1 Main aspects to be included in the national guidelines

- Fully informed written patient consent with a right to refuse
- All representatives should have the BTEC professional theatre or hospital access qualification, and should carry evidence of passing a criminal records bureau check
- Representatives should meet the patients before the procedure and explain the reason for their attendance, their training in matters of confidentiality and patient safety, and provide appropriate literature as necessary
- All visits to the operating theatre should be prebooked and agreed with the person in charge of theatre
- All representatives should wear photographic identification, sign in and be chaperoned throughout their time in the operating theatre

The consequence of not paying attention to these issues can be seen by the adverse response in the media provoked by a recent paper describing medical students performing intimate examinations without consent.[10] We need to set even more scrupulous standards for non-clinicians who have commercial, not clinical, priorities. This will protect patients, clinicians and representatives.

Patients are more likely to agree to the presence of representatives in the operating theatre if the patients can be assured that the representatives have been trained. The BTEC professional theatre or hospital access qualification has provided external validated training since 2002.[11] Modules cover consent, confidentiality, patient and staff safety issues, and knowledge of local and national regulations. Only 2 of 79 respondents, however, referred to this qualification in their response.

Most of the senior nurses in this survey are in favour of having uniform guidelines to cover the visits by representatives. Although a few hospitals are attempting to meet this need, it is clear that national guidance covering both the NHS and private sector would clearly be helpful. It would be appropriate to consult patients on the constituents of the guidelines. Table 1 details the main aspects that the respondents thought should be covered. A guideline would assure consistency and would make monitoring of compliance possible. The surgical device companies would have a uniform standard for their representatives to meet, which would help protect them from adverse outcomes and publicity.

CONCLUSION

It is in the interest of patients to have the technical knowledge of surgical device representatives on hand when new equipment is being used in the operating theatre. We, however, need to discuss this need openly with patients and obtain their fully informed consent. Respect for patients' individuality, privacy and dignity should be at the forefront of clinicians' minds.

Currently, only a few hospitals meet the legal, ethical and safety standards required when non-clinicians visit operating theatres. A national guideline should be disseminated to protect patients, staff, hospitals and representatives. It is clearly in no one's interest if patients' confidence is diminished when undergoing surgery.

Competing interests: None declared.

Ethical approval: Not required as this was an audit. This was an anonymous postal survey of senior hospital staff only, requesting details of their units' practice. No research was carried out.

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